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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET  
HÄSSLE, ASTRAZENECA LP, KBI INC.,  
and KBI-E INC.,

Plaintiffs and  
Counterclaim Defendants

v.

HANMI USA, INC., HANMI  
PHARMACEUTICAL CO., LTD., HANMI FINE  
CHEMICAL CO., LTD, and HANMI  
HOLDINGS CO., LTD.,

Defendants and  
Counterclaim-Plaintiffs.

Civil Action No. 3:11-cv-00760-JAP-TJB

Hon. Joel A. Pisano, USDJ  
Hon. Tonianne J. Bongiovanni, USMJ

**PLAINTIFFS' BRIEF IN OPPOSITION TO HANMI'S  
MOTION IN LIMINE NO. 4 (TO PRECLUDE ASTRAZENECA  
FROM ATTEMPTING TO INTRODUCE EVIDENCE ALLEGING  
INVALIDITY OR UNENFORCEABILITY OF HANMI'S PATENTS)**

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Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc. (“AstraZeneca”) hereby oppose defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.’s (“Hanmi”) motion *in limine* “No. 4” seeking to preclude AstraZeneca from challenging Hanmi’s assertion that its separate patenting of its esomeprazole strontium tetrahydrate is evidence of substantial differences from the claimed invention.

### **INTRODUCTION**

Hanmi’s motion is an effort improperly to shield its expected trial witnesses from legitimate cross examination. If Hanmi relies on its later patents to support its argued substantial differences between its proposed products and the patent claims at issue to rebut AstraZeneca’s doctrine of equivalents case, examination on those patents is both proper and fair. Hanmi, not AstraZeneca has injected the Hanmi patents into this litigation. AstraZeneca has no intention in this litigation of seeking any rulings concerning the validity or enforceability of Hanmi’s patents, but should be allowed to challenge Hanmi’s evidence.

As explained below, Hanmi’s evidence of its separate patenting has no probative value under the circumstances here. To the extent that evidence is considered, questions about the Hanmi patents, what they cover, and how they were obtained are fair subjects of inquiry. For these reasons, Hanmi’s motion *in limine* No. 4 should be denied.

#### **I. Evidence of Hanmi’s Separate Patenting Has No Probative Value Here, In View of the Insubstantial Differences Between Hanmi’s Claimed Strontium Salt and the Claimed Alkaline Salts**

Hanmi asserts that its separate patenting of its esomeprazole strontium tetrahydrate is highly relevant evidence supporting substantial differences between its product and the claimed invention. However, the mere later patenting of a product covered by earlier

broad patent claims does not establish substantial differences. Indeed, it is common for a patented product to infringe other earlier granted patent claims that are broader in scope.<sup>1</sup>

The law embraces such sequential patenting on overlapping subject matter:

Selection inventions, also referred to as “improvement patents,” are a normal consequence of technological progress . . . . Inventions based on the identification or selection of a specific material or compound with particularly desirable properties within a previously disclosed genus of such materials or compounds do not violate any of the substantive requirements of patentability.<sup>[2]</sup>

A later selection patent does not confer on the later inventor the right to use his patented product, but only confers the right to exclude others from practicing the later-claimed selection invention. *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984) (“A patent is not the grant of a right to make or use or sell. . . . It grants only the right to exclude others.”) (citation omitted). That is the situation here. Although Hanmi obtained later patents on its specific solid state tetrahydrate form of esomeprazole strontium, it cannot make, use and sell its products with impunity simply because it obtained a patent. That commercial activity may still infringe AstraZeneca’s earlier patents asserted in this litigation. In fact, Hanmi relies on authority that recognizes as much. *Roton Barrier Inc. v. Stanley Works*, 79 F.3d 112, 1127 (Fed. Cir. 1996) (concurring opinion) (“It is a truism that the fact that an accused device is itself patented does not preclude finding that such a device infringes an earlier patent of another.”).

Where a defendant has “appropriated the material features of [an earlier patented invention], infringement [under the doctrine of equivalents] will be found even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement.” *Atlas Powder*, 750 F.2d at 1580 (citation omitted).

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<sup>1</sup> See, e.g., *In re Ruschig*, 343 F.2d 965, 974-75 (C.C.P.A. 1965) (prior generic invention did not anticipate later-selected species); *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994) (prior generic invention did not render later-selected species obvious under 35 U.S.C. § 103); *In re Kaplan*, 789 F.2d 1574, 1578, 1580 (Fed. Cir. 1986) (prior generic patent claim did not invalidate claim to later-selected species for double patenting).

<sup>2</sup> *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 364 F. Supp. 2d 820, 897 (S.D. Ind. 2005).

Here, the evidence will show that Hanmi misappropriated the material features of AstraZeneca's inventions. The AstraZeneca patents claim a solid state salt made from anionic esomeprazole and a cation. Hanmi's product is merely a solid state salt of anionic esomeprazole and a **strontium** cation instead of one of the exemplified cations in the '504 patent. Hanmi's strontium salt nonetheless performs the same function, in the same way to achieve the same result as AstraZeneca's invention.

Hanmi relies on *Roton Barrier* to suggest that later patenting necessarily negates a finding of infringement by equivalence. However the ruling in *Roton Barrier* rested on the fact that the later-patented accused device differed substantially from the earlier-patented asserted claim because the claimed "recesses [were] offset in contradistinction to the plain language of claim 1." 79 F.3d at 1127 (Fed. Cir. 1996). Also, other courts have found later patenting to be immaterial to the infringement inquiry. *Fiskars, Inc. v. Hunt Mfg Co.* 221 F.3d 1318, 1324 (Fed. Cir. 2000) ("it is well established that separate patentability does not avoid equivalency as a matter of law"); *see also Atlas Powder*, 750 F.2d at 1580-81. And any interpretation of *Roton Barrier* as suggesting that attempts to design around an existing patent should count against infringement is questionable. *See, e.g., DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1334 (Fed. Cir. 2001) ("The district court concluded that an inference of no infringement under the doctrine of equivalents arises when a competitor attempts to design around a patent. Such a conclusion is clearly inconsistent with the Supreme Court's decision in *Warner Jenkinson [Co., Inc. v. Hilton Davis Chemical Co.]*, 520 U.S. [17,] 36 [(1997)].").

Hanmi's assertion that its esomeprazole strontium tetrahydrate has certain specific properties beyond those claimed and discussed in AstraZeneca's patents-in-suit, sufficient to support a new patent, does not automatically negate infringement and is immaterial here, where

Hanmi's salt exhibits the same advantages that the claimed salts exhibit over the prior art forms of esomeprazole and omeprazole.

## **II. The Prosecution History of Hanmi's Patent Shows That Hanmi's Separate Patenting Does Not Evidence Substantial Differences**

To the extent the Court decides to consider Hanmi's evidence of later patenting, the weight given to such evidence should only be considered in light of the scope of the later claims and the circumstances in which they were prosecuted and obtained. Hanmi's own cited authority recognizes that the potential relevance of a later patent to the substantial differences inquiry "depend[s] on its subject matter." *Roton Barrier*, 79 F.3d at 1127 (Fed. Cir. 1996) (concurring opinion).

Contrary to Hanmi's suggestion, Hanmi did not obtain its patent by demonstrating that the strontium salt of esomeprazole was substantially different from AstraZeneca's claimed alkaline salts. Rather, the focus of prosecution concerned the differences between Hanmi's specific tetrahydrate form of esomeprazole strontium and a form of esomeprazole strontium that was prior art to Hanmi's patent.

During prosecution, the patent examiner rejected Hanmi's broad claims to crystalline esomeprazole strontium hydrate as obvious over published international patent application WO 2006/120520 to Bhirud ("Bhirud"), which is directed to the "strontium salt of esomeprazole," processes for its preparation and its uses in pharmaceutical formulations and methods of treatment, in view of other prior art. **Exh. 1**, June 25, 2008 Office Action in the prosecution of Hanmi Patent No. 7,576,219 at 2 (HAN00023737). Hanmi thereafter limited its claims to its specific esomeprazole strontium tetrahydrate product. Thus, Hanmi's assertion that the Hanmi patent claims were allowed because they recited a different salt from those claimed in AstraZeneca's asserted patents mischaracterizes the scope of Hanmi's later patent claims and the

events underlying their prosecution and issuance. Specifically, Hanmi's later patent claims were allowed because they were limited to a *specific solid state form* of an alkaline salt of esomeprazole.

Also, notably, the Bhirud prior art patent application (disclosing esomeprazole strontium) never issued as a U.S. patent, undermining Hanmi's argument that the strontium salt of esomeprazole is separately patentable from the claimed alkaline salts. Consistent with that, Hanmi also never sought a broad claim to esomeprazole strontium in the United States, as it had in an international application. See **Exh. 2**, WO 2007/049914 claim 1. As noted, when Hanmi filed its U.S. application which led to the patents on which Hanmi relies here, it had already narrowed its claim to "[a] crystalline S-omeprazole strontium hydrate" which it subsequently further narrowed to obtain patentability. Hanmi's decision not to seek a claim to the strontium salt of esomeprazole indicates that Hanmi did not consider the strontium salt of esomeprazole to be separately patentable over AstraZeneca's patents-in-suit.

### **III. Hanmi Has Put Its Patents In Issue Here**

Hanmi intends to offer fact witnesses who will testify about Hanmi's patents, yet it seeks to preclude AstraZeneca from cross-examining those same witnesses on the same subject matter. By asserting that the grant of its patents is evidence of non-infringement, Hanmi has put those patents squarely at issue in this case, and AstraZeneca should have the right to place Hanmi's evidence in the appropriate light.

### **CONCLUSION**

For the foregoing reasons, Hanmi's Motion in Limine No. 4 should be denied.

Respectfully submitted,



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**CERTIFICATE OF SERVICE**

I hereby certify that on May 6, 2013, I caused a copy of the foregoing **PLAINTIFFS' BRIEF IN OPPOSITION TO HANMI'S MOTION IN LIMINE NO. 4** and supporting documents to be served upon the following counsel by operation of the Court's electronic filing system and/or electronic mail:

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